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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,710	08/05/2003	Richard J. Yarwood	RPS6017C2	1897
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Fitzpatrick Cella (Catalent) 30 Rockefeller Plaza New York, NY 10112			EXAMINER SOROUSH, ALI	
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			12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/635,710

Applicant(s)

YARWOOD ET AL.

Examiner

Ali Soroush

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 09/26/2007 to the Office Action mailed on 03/26/2007 is acknowledged.

Status of the Claims

Claims 1-23 and 39 have been cancelled and claims 24-38 have been amended. Therefore, claims 24-38 are currently pending examination for patentability.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejections of claims 24-39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of the amendment submitted with aforementioned response.

Double Patenting

1. The rejection of claim 39 under 35 U.S.C. 101 as claiming the same invention as that of claim 17 of prior U.S. Patent No. 6,726,928 B2 is **withdrawn** in light of the amendment submitted with aforementioned response.

2. The rejection of claims 24-38 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 4-16 of U.S. Patent No. 6,726, 928 B2 is **maintained**. Applicant's argument that once all other issues

concerning the pending application have been addressed they will then file a terminal disclaimer is acknowledged. The rejection is therefore maintained until the terminal disclaimer is filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. The rejection of claims 24, 26, 27, 28, 29, 31, 35, 37, and 38 under 35

U.S.C. 102(e) as being anticipated by Ecanow (US 5,382, 437, Published 01/17/1995)

is **withdrawn** in light of applicants amendment.

Response to Applicants Arguments

Applicant argues that Ecanow does not teach the use of water or an alcoholic solvent to suspend the active agent and carrier material in. Ecanow teaches the use of an aqueous 10% ammonium solvent for the suspension of the active agent and carrier material. Applicants have amended claim 24 to limit the solvents to only water and alcoholic solvents. Applicant's arguments and amendments have been fully considered and have been found to be persuasive. This amendment and applicants argument has necessitated the withdrawal of the rejection claims 24, 26, 27, 28, 29, 31, 35, 37, and 38 under 35 U.S.C. 102(e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. The rejection of claims 24, 26-30, 32-34, and 36 under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US 4305502, Published 12/15/1981) in view of Ince et al. (US 4657929, Published 04/14/1987) **is maintained**.

Applicant Claims

Applicant claims a process for the preparation of a solid, rapidly disintegrating dosage form comprising a pharmaceutically active substance in an aqueous or alcohol solvent and further comprising a carrier materials (i.e. gelatin), rendering the active substance less soluble. The process further comprises the composition being filled into a plurality of mold pockets in a film and frozen, which is further freeze-dried, or vacuum dried to remove the solvent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Gregory et al. teaches, "The invention relates to packages containing shaped articles carrying chemicals, particularly to pharmaceutical dosage forms carrying pharmaceuticals. The shaped articles, which disintegrate rapidly in water are contained in depressions in sheets of filmic material and are enclosed by a covering sheet adhering to the filmic material." (See abstract). "The shaped articles are prepared by a process which comprises subliming solvent from a composition comprising the chemical (e.g. pharmaceutical substance) and a solution of carrier material in a solvent ..." (See column 3, Lines 21-25). "The carrier material can be any water soluble or water dispersible material that is pharmacologically acceptable or inert to the chemical and which is capable of forming a rapidly disintegratable open matrix network." (See column 2, Lines 53-57). "A particularly advantageous carrier may be formed from polypeptides such as gelatin..." (See column 2, Lines 60-62). "The solvent is preferably water but it may contain a cosolvent (such as alcohol e.g. tert-butyl alcohol) ..." (See column 3, Lines 32-34). Gregory further teaches, "A measured quantity of the composition may be added to each depression and the filmic material containing the filled material then cooled ... When the contents of the depressions are frozen the filmic and contents may be subjected to reduced pressure ...to aid the sublimation." (See column 5, Lines 12-20). "A large sheet of filmic material ... containing numerous depressions may be subjected to the freeze drying procedure and the covering sheet may then be adhered to it." (See column 5, Lines 24-26). The method of formulation of a pharmaceutically active agent into a readily dissolving, orally administered tablet taught by Gregory et al.

has the inherent property of rendering the active substance less soluble and more palatable. Therefore, it would be expected that an identical process, such as that taught by Gregory et al., would necessarily also render the active substance less soluble and more palatable.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Gregory et al. lacks a teaching of the active substance being domperidone. Ince et al. cure this deficiency. Gregory et al. lacks an anticipatory teaching of freeze-drying to remove solvent following freezing of the composition. Gregory et al. however makes such a teaching obvious.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

Ince et al. teaches a composition that comprises a 4-hydroxy phenethylamines and optionally other pharmaceutically active substances. (See abstract and column 10, Lines 59-64). One such example of an additional compound to be used in the composition is domperidone. (See column 11, Lines 1-11). The composition can be made into tablets and capsules further include adjuvants and carriers including gelatin. (See column 11, Lines 32-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Gregory et al. and Ince et al. One would have been motivated to do this so that the composition of Ince et al. could be formed into a blister pack of tablets for dispensing to a patient. Wherein the advantage of doing so by the process of Gregory et al. would "enable packages of the

shaped articles to be produced in which the handling of the individual shaped articles may be eliminated until the user ... removes the product from the depression in the package immediately prior to use." (See Gregory et al. column 4, Lines 1-6). Gregory et al. teaches the use of freeze-drying and freezing composition in the package. However, Gregory et al does not teach freeze-drying followed by the freezing step. It would have been obvious to one of ordinary skill in the art to combine the two steps. One would have been motivated to do this in order to get the additive effect of the steps in removing the solvent from the composition. For the foregoing reasons the instantly claimed process and composition are made obvious.

Response to Applicants Arguments

Applicant argues that Gregory et al. teaches that it is desirable that the active ingredient be readily soluble and therefore teaches away from applicants own invention. Applicant's argument has been fully considered and found not to be persuasive. Gregory et al. teaches, "the chemical **may be** a water-soluble or water-dispersible pharmaceutical ..." (See column 1, Lines 37-38). Gregory et al. therefore only teaches that the chemical/pharmaceutical can be a water-soluble drug but can also be a water-insoluble drug. In fact Gregory et al. teaches the use of Lorazepam to practice the invention of Gregory et al. Koparkar et al. (US Patent 5284662, Published 02/08/1994) teaches that Lorazepam is a slightly soluble pharmaceutically active agent (See column 2, Lines 25-26 and column 3, Lines 15-34) and Chen et al. (US Patent 7125564 B2, Published 10/24/2006) teaches that Lorazepam is a poorly water soluble drug (See

column 6, Lines 42-50). Therefore, the applicant's assertion that Gregory et al. teaches away from the instant invention is not found persuasive. Applicant further argues that Gregory et al. does not teach the active agent being rendered less soluble and that the examiners position that it is inherent to the method taught by Gregory et al. has not meet the requirements necessary in relying upon a theory of inherency. Applicant's arguments have been fully considered and found not to be persuasive. The action of a active agent being rendered less soluble is a mechanism of the interaction of the active agent with the other constituents of composition and the method of tableting such a composition. Since, Gregory et al. teaches that the tablet is formed by mixing the active agent with a solvent and a carrier material that is water-soluble or water dispersible and then the mixture is tableted by a freezing-drying method it would be expected that such a process would render the active agent less soluble. It is therefore a characteristic of the method described in Gregory et al. to render the active agent less soluble which would be desirable for tableting. For the foregoing reasons the rejection of claims 24, 26-30, 32-34, and 36 under 35 U.S.C. 103(a) is maintained.

New Grounds of Rejection

2. Claims 24-34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US 4305502, Published 12/15/1981) in view of Mughal (US 4465838, Published 08/14/1984).

Applicant Claims

Applicant claims a process for the preparation of a solid, rapidly disintegrating dosage form comprising a pharmaceutically active substance in an aqueous or alcohol solvent and further comprising a carrier materials (i.e. gelatin), rendering the active substance less soluble. The process further comprises the composition being filled into a plurality of mold pockets in a film and frozen, which is further freeze-dried, or vacuum dried to remove the solvent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Gregory et al. teaches, "The invention relates to packages containing shaped articles carrying chemicals, particularly to pharmaceutical dosage forms carrying pharmaceuticals. The shaped articles, which disintegrate rapidly in water are contained in depressions in sheets of filmic material and are enclosed by a covering sheet adhering to the filmic material." (See abstract). "The shaped articles are prepared by a process which comprises subliming solvent from a composition comprising the chemical (e.g. pharmaceutical substance) and a solution of carrier material in a solvent ..." (See column 3, Lines 21-25). "The carrier material can be any water soluble or water dispersible material that is pharmacologically acceptable or inert to the chemical and which is capable of forming a rapidly disintegratable open matrix network." (See column 2, Lines 53-57). "A particularly advantageous carrier may be formed from polypeptides such as gelatin..." (See column 2, Lines 60-62). "The solvent is preferably water but it may contain a cosolvent (such as alcohol e.g. tert-butyl alcohol) ..." (See column 3, Lines 32-34). Gregory further teaches, "A measured quantity of the composition may be

added to each depression and the filmic material containing the filled material then cooled ... When the contents of the depressions are frozen the filmic and contents may be subjected to reduced pressure ...to aid the sublimation.” (See column 5, Lines 12-20). “A large sheet of filmic material ... containing numerous depressions may be subjected to the freeze drying procedure and the covering sheet may then be adhered to it.” (See column 5, Lines 2426). In a preferred example Gregory et al. teaches that the active agent is oxaprozin and Lorazepam. (See column 5, example 1 and column 6, example 3). The method of formulation of a pharmaceutically active agent into a readily dissolving, orally administered tablet taught by Gregory et al. has the inherent property of rendering the active substance less soluble and more palatable. Therefore, it would be expected that an identical process, such as that taught by Gregory et al., would necessarily also render the active substance less soluble and more palatable.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Gregory et al. lacks a teaching of the active substance being presented in a less soluble form prior to formation of said system. Mughal cures this deficiency.

Mughal teaches that oxaprozin has a very bitter taste and teaches a method of forming a insoluble calcium oxaprozin which is less bitter. (See column 1, Line 11 and Lines 28-40).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Gregory et al. with Mughal. One would have been motivated to do so because Mughal teaches the use of this insoluble oxaprozin would provide a tablet that does not have a bitter taste. For the foregoing reasons the instantly claimed process and composition are made obvious.

3. Claims 24-35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US 4305502, Published 12/15/1981) in view of Kroparkar et al. (US 5284662, Published 02/08/1994) .

Applicant Claims

Applicant claims a process for the preparation of a solid, rapidly disintegrating dosage form comprising a pharmaceutically active substance in an aqueous or alcohol solvent and further comprising a carrier materials (i.e. gelatin), rendering the active substance less soluble. The process further comprises the composition being filled into a plurality of mold pockets in a film and frozen, which is further freeze-dried, or vacuum dried to remove the solvent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Gregory et al. is disclosed above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Gregory et al. lacks a teaching of the active substance being loperamide.

Kroparkar et al. cures this deficiency.

Kroparkar et al. teaches an oral sustained release composition having an active agent including lorazepam and loperamide. (See abstract and column 3, Lines 15-34 and column 4, Line 9).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Gregory et al. with Kroparkar et al. One would have been motivated to do so because Kroparkar et al. teaches that lomperamide and lorazepam are suitable alternatives. Therefore, if one wanted to formulate a fast disintegrating dosage form of lomperamide one would look to the teachings of Gregory et al. and Korparkar et al. For the foregoing reasons the instantly claimed process and composition are made obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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